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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA
PHILADELPHIA DIVISION

UNITED STATES OF AMERICA; STATE OF FLORIDA; STATE OF NEW YORK; COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; COMMONWEALTH OF VIRGINIA; STATE OF DELAWARE; STATE OF ILLINOIS; STATE OF NEVADA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF INDIANA; STATE OF MONTANA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF OKLAHOMA; STATE OF RHODE ISLAND, STATE OF TENNESSEE; and STATE OF TEXAS *ex rel.* PEGGY RYAN,

Plaintiffs,

v.

ENDO PHARMACEUTICALS INC.

Defendant.
_____/

CASE NO.: 05-3450
FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

THIRD AMENDED FALSE CLAIMS ACT *QUI TAM* COMPLAINT

1) This is an action brought by the Plaintiff/Relator on behalf of the United States of America pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq* (the "FCA"), and on behalf of the above captioned states under their respective State False Claims Acts. The false claims at issue were caused to be made by the Defendant, Endo Pharmaceuticals Inc., by marketing and promoting the off-label use of the drug Lidoderm in violation of federal and state statutes and regulations.

2) The FCA provides that any person who knowingly submits or causes to be submitted to the government or recipients of federal funds a false or fraudulent claim for payment or approval is liable for a civil penalty of between $5,500 and $11,000 for each such claim, and three times the amount of the damages sustained by the government. The False Claims Act Statutes permit persons having information regarding a false or fraudulent claim against the government to bring an action on behalf of the government and to share in any recovery. The complaint must be filed under seal, without service on the defendant. The complaint remains under seal while the government conducts an investigation of the allegations in the complaint and determines whether to join the action.

3) Pursuant to the False Claims Acts, plaintiff/relator seeks to recover on behalf of the United States and the states listed in this complaint, damages and civil penalties arising from Medicaid and Medicare payments for Lidoderm prescriptions for unauthorized, off-label use. Defendant, by marketing and promoting Lidoderm for unapproved off-label use, caused thousands of claims to be submitted to Medicaid and Medicare for reimbursement of Lidoderm prescriptions, when those prescriptions were not eligible for Medicaid or Medicare reimbursement.

PARTIES

4) Relator Peggy Ryan is a resident of the state of New York and an employee of Defendant Endo Pharmaceuticals Inc. ("Endo"). Ryan is the original source of information and facts set forth herein concerning the actions of Endo, and the facts set forth herein are based on Ryan's personal knowledge.

5) Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Chadds Ford, Pennsylvania. Endo manufactures, markets and sells

pharmaceuticals and has a dedicated sales force of approximately 700 sales representatives and additional contract sales representatives throughout the United States, including those states listed in this complaint. Endo has marketed its branded pharmaceutical products to high-prescribing physicians in areas including but not limited to pain management, neurology, orthopedic surgery, neurosurgery, anesthesiology, oncology, rheumatology, and primary care. Endo's sales force also targets retail pharmacies and other healthcare professionals in states across the country.

JURISDICTION AND VENUE

6) This action arises under the False Claims Act, 31 U.S.C. § 3729 et seq. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 31 U.S.C. § 3730, and 28 U.S.C. § 1345. This Court has jurisdiction over the State False Claims Act claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

7) This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Defendant can be found in, resides in, or has transacted business in the Eastern District of Pennsylvania.

8) Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant can be found in, resides in, or has transacted business in the Eastern District of Pennsylvania, and many of the alleged acts occurred in this District.

FACTS

9) The Medicaid and Medicare programs tightly restrict the types and uses of drugs eligible for purchase using Medicaid and/or Medicare funds. Federal regulations further prohibit drug companies from marketing practices that could lead to unnecessary or ineffective

prescription of drugs. These regulations are intended to ensure that Medicaid and Medicare funds are only used to purchase drugs that have been determined to be safe and effective for treatment of specific conditions.

10) Relator Peggy Ryan alleges in this *qui tam* action that Defendant Endo has undertaken a course of action that it knew would cause numerous violations of federal and state statutes and regulations relating to reimbursement for Lidoderm, an Endo product. Endo does not write the prescriptions or provide Lidoderm to the Medicaid and Medicare programs. Rather, Endo intentionally undertook a course of conduct that Endo knew would lead to the submission of thousands of ineligible Medicaid and Medicare claims for Lidoderm prescriptions. Many of the pharmacists and physicians submitting claims for Lidoderm prescriptions were likely unaware that the claims were ineligible for Medicaid and/or Medicare reimbursement, but Endo was fully aware that its actions would lead to providers submitting false claims to the federal and state governments.

Regulatory Background

11) Pharmaceutical drugs cannot be sold in the United States until the Food and Drug Administration ("FDA") has concluded that a drug is safe and effective at specific dosages. The FDA-approved indications and dosages are set forth on an approved drug's label. Physicians may prescribe FDA-approved drugs for indications, or at dosages, that vary from those set forth on the label, but drug companies are prohibited under the Food, Drug, and Cosmetic Act from marketing or promoting approved drugs for uses other than the approved uses set forth on the label. 21 U.S.C.§ 355(a) & (d). Distribution of prescription drugs for off-label uses is expressly prohibited. 21 U.S.C. § 331(d).

12) Federal law limits Medicaid reimbursement for prescription drugs to "covered outpatient drugs." 42 U.S.C. § 1396b(I)(10). Only drugs used for "medically accepted indications" qualify as covered outpatient drugs. 42 U.S.C. § 1396r-8(k)(3). Only an FDA-approved use, or one that is supported by express compendia set forth in the Medicaid statute, is a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(g)(1)(B)(I). Similarly, federal law limits Medicare reimbursement for "covered Part D drugs." 42 U.S.C. §1395w-102(e). In order for a prescription drug to be a "covered Part D drug" it must be used and sold in the United States and used for a "medically accepted indication" as defined by 42 U.S.C. §1396r-8(k)(6); 42 U.S.C. §1395w-102(e). As mentioned above, only an FDA approved use, or one that is supported by express compendia set forth in the federal statute is a "medically accepted indication." 42 U.S.C. §1396r-8(k)(6).

13) Federal anti-kickback laws, 42 U.S.C. § 1320a-7b(b), also regulate the marketing of pharmaceuticals to prevent overutilization of prescription drugs. Drug companies are prohibited from offering or paying remuneration, cash or otherwise, to induce physicians or others to recommend or prescribe drugs that may be paid for by federal programs such as Medicaid or Medicare. 42 U.S.C. § 1320a-7b(b). Improper and illegal inducements include payment of "research grants," paying physicians for "studies," or any payments that are based on the volume of prescriptions written.

14) Additionally, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Govt. Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia False Medicaid Claims Act, 49 Ga. Code Ann. Ch. 4 at 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*,

Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1 *et seq*., Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq*., Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12 § 5A *et seq*., Montana False Claims Act, Mont. Code Ann. § 17-8-403(1) *et seq*., Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq*., New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq*., New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-4 *et seq*., New Jersey False Claims Act, N.J.S.A. §2A:32C *et seq*., New York False Claims Act, N.Y. State Fin. Law § 189 *et seq*., Oklahoma Medicaid False Claims Act § 63-5053.1 *et seq*., Rhode Island State False Claims Act 9-1.1-3 *et seq*., Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq*., Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq*., and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

Endo's Marketing of Lidoderm for Off-Label Use

15) In September 1999 Endo introduced a new product, Lidoderm. Lidoderm is a patch that contains 5% lidocaine, an analgesic. The FDA has approved Lidoderm only for use in the relief of postherpetic neuralgia ("PHN"). PHN is a complication that afflicts some victims of herpes zoster, commonly known as shingles. Approximately 20% of shingles victims suffer from PHN, which results in severe pain lasting months or years after the initial shingles rash has cleared up. The older the shingles victim, the more likely it is that the victim will suffer from PHN.

16) Lidoderm treats PHN by allowing for the lidocaine contained in the patch to directly treat the affected nerves. The patch, consisting of an adhesive material containing 5%

lidocaine and a polyester backing, is applied to intact skin. The lidocaine is then released into the dermal and epidermal layers of the skin, where it reaches the damaged nerves and provides pain relief. The patch delivery system greatly reduces the amount of lidocaine entering the bloodstream and also avoids numbness and the complete loss of sensation in the treated area. Lidoderm is the only topical treatment for PHN that has been approved by the FDA.

17) The market for Lidoderm is inherently limited by the relatively low numbers of Americans who suffer from PHN in a given year, approximately 200,000. As a result, Endo sought to increase the profitability of Lidoderm by encouraging its use to treat a variety of ailments, such as carpal tunnel syndrome, lower back pain, osteoarthritis and numerous other conditions. In furtherance of this goal, Endo formulated call plans which identify physicians to be contacted by sales representatives. These plans clearly indicate that Lidoderm sales representatives were being instructed by Endo to target physicians who specialize in areas of medicine that do not typically deal with the treatment of PHN patients. Through these call plans, Endo actively promoted the writing of Lidoderm prescriptions by physicians for off-label purposes by directing its sales force to focus promotional efforts on physicians who specialize in the treatment of conditions other than PHN. Endo sales representatives continue to follow the illegal marketing schemes outlined above, resulting in continued improper reimbursements from government healthcare programs.

18) Additionally, incentive compensation scorecards are provided by Endo to sales representatives on a monthly basis. These scorecards pressured Endo's sales representatives to attain unrealistic Lidoderm sales goals. Bonuses were awarded based on the representatives' Lidoderm sales. Because the market for on-label sales for Lidoderm is saturated and the off-label market is the only area in which there is room for growth, the unavoidable implication of Endo's

incentive compensation scorecards is that the off-label market is aggressively targeted. At all times relevant to this Complaint, the only way Endo sales representatives could meet the quotas set for them by management was by promoting Lidoderm off-label.

19) When Relator was first hired at Endo as a Specialty Sales Representative, she was required to keep a "Restricted Materials Log," which recorded the identities of doctors to whom restricted sales materials regarding the off-label use of Lidoderm were distributed. In July 2004, Endo's Specialty District Manager, Bill Kellens, wrote an email in which he expressed criticism of Kimberly Konopa, a specialty sales representative, for not logging enough entries on her "Restricted Materials Log." This email is illustrative of a form of pressure used on Endo's sales force to increase the distribution of studies concerning off-label uses for Lidoderm. The use of these logs was abruptly discontinued by Endo in 2004. It is Relator's belief that Endo terminated the use of the logs upon the realization that they could serve as evidence of Endo's off-label promotion of Lidoderm.

20) In October 2005, Endo's Lidoderm Project Manager, Ed Tell, sent the sales force an email instructing them to "seize the opportunity that currently exists in the market" due to the withdrawal of Vioxx and Bextra. Vioxx and Bextra were never indicated for the treatment of PHN, the only approved on-label use for Lidoderm; therefore, their withdrawals from the market could not have created any opportunities to increase on-label sales of Lidoderm, and Mr. Tell could only have been referring to the sales representatives' potential to increase off-label sales of Lidoderm, which is further proof of Endo's scheme to promote Lidoderm for use beyond its single FDA-approved indication.

21) Additional support of Relator's allegations can be found in conversations between Relator and other Endo employees. In August 2005, Relator and Endo District Sales Manager,

Gail Pierce, visited several physicians and nurse practitioners wherein Pierce improperly informed them of various off-label Lidoderm uses. When one of the nurse practitioners greeted Pierce by informally asking "what's new," Pierce proceeded to explain several newly discovered off-label uses for Lidoderm. Pierce later explained to Relator that the nurse practitioner's mere greeting illustrated one of the "loopholes" for circumventing FDA off-label advertising regulations. Pierce had previously given a lecture on those loopholes at an Endo sales meeting in Arizona.

22) During another discussion of off-label activity at Endo, Pierce mentioned to Relator that when she first learned of a recent FDA warning letter sent to Endo, she feared that it referred to off-label advertising violations, but was relieved to learn that it merely referred to exaggerated efficacy claims. She attempted to assuage Relator's concerns regarding Endo's off-label sales by commenting that it would be unusual for the FDA to investigate a company like Endo for off-label promotion, as such inquiries usually target the larger pharmaceutical companies like Pfizer.

23) During a conversation with Endo Managed Markets Representative Rich Karelas in September 2005, Relator was told that Endo's home office staff was "completely paranoid" because of the high percentage of off-label Lidoderm sales, and was concerned that someone may complain to the government regarding Endo's sales improprieties. Karelas also stated that Scott Shivley, an Endo Senior Vice President, was forced out of the company and had access to corporate documents that could be very detrimental to Endo if they ended up in the "wrong hands." During another conversation, Karelas told Relator that he attended a meeting during which a Medicaid representative raised questions regarding the inordinate amount of reimbursements for Lidoderm prescriptions. Karelas told Relator that he assured the Medicaid

representative that Endo does not train its sales staff to encourage off-label use of Lidoderm, and then commented to Relator, "wink, wink," which Relator took as an acknowledgement that Karelas deceived the Medicaid representative.

24) At a September 2005 Plan of Action meeting in Syracuse, New York, J.P. Brassil, an Endo Regional Business Director, stated that 90 percent of all Lidoderm prescriptions are off-label. Brassil also brought up different techniques to improperly provoke discussions with doctors regarding the off-label use of Lidoderm. Brassil went on to say that Endo is currently on the radar screen because it had become a $400 million company dealing with pain medications. During the meeting, Endo's District Manager, Anthony Luongo, explained to Relator that Endo was "too far gone" in the area of off-label sales to change its ways. He told Relator that in the event Endo was accused of encouraging off-label Lidoderm sales, its explanation would be that it is incapable of controlling what doctors prescribe.

25) In April 2006, Relator had conversations with Deanne Melloy, Endo's Senior Director of Marketing for Lidoderm, and Bill Kellens, Endo's Lidoderm Project Manager. During these conversations, Kellens stated that between 97-98 percent of all Lidoderm prescriptions are off-label, and discussed how orthopedic surgeons, who rarely, if ever, treat PHN patients, were going to be added to Endo sales force call plans. Melloy told Relator that Endo "wined and dined" doctors at an upscale hotel two years prior, and that she was currently arranging a similar excursion. She also stated that she was aware that 50 carpal tunnel studies had been disbursed to the Lidoderm sales force even though "they're not supposed to have it."

26) Although Endo is currently pursuing studies and clinical trials to determine the effectiveness of Lidoderm in the treatment of conditions other than PHN, Lidoderm has not been approved by the FDA to treat any conditions other than PHN. Endo's decision not to seek FDA

approval for indications other than the treatment of PHN has been motivated, at least in part, by its desire to maintain Lidoderm's orphan drug status. An orphan drug is a pharmaceutical agent that has been developed to treat a rare medical condition which affects fewer than 200,000 people in the United States. If Lidoderm were to lose its orphan drug status, Endo would lose certain tax incentives and the right to sell the drug without competition. Therefore, in order to increase Lidoderm sales without jeopardizing its orphan drug status, Endo decided to engage in off-label marketing to encourage doctors to use Lidoderm for the treatment of conditions other than PHN. This improper marketing practice did increase Lidoderm sales significantly while simultaneously allowing Endo to reap the benefits of Lidoderm's orphan drug status.

27) Endo has sought to exploit a loophole in the FDA rules concerning off-label marketing. FDA rules permit drug manufacturers to distribute publications created by neutral third parties that describe the results of off-label uses when such publications are requested by physicians. Endo sought to fraudulently misapply these rules through a strategy of creating articles, studies, publications, and programs that touted the effectiveness of Lidoderm in a variety of off-label uses, but that would appear to be the product of neutral third parties.

28) For example, Endo announced in 2004 that the results of two pilot studies suggested that Lidoderm was effective in treating low back pain and osteoarthritis. The studies and trials involving the off-label use of Lidoderm were not neutral clinical trials, however. Instead, Endo has financed and directed the studies and trials of Lidoderm for the treatment of conditions other than PHN. Endo presents and publicizes the results of trials and studies it has controlled as if those results were the product of independent, objective, third-party studies and trials. Endo's intent in publicizing these results is to encourage physicians to prescribe Lidoderm for unapproved, unauthorized, off-label use; indeed, a review of the identified studies and related

literature revealed that the release of off-label studies funded by Endo in 2003, 2004, 2005, and 2006 directly preceded demonstrable sales increases of Lidoderm.

29) At least fourteen studies pertaining to the efficacy of Lidoderm have been conducted. Of those fourteen studies, eleven were sponsored by, or linked directly to, Endo or Dr. Harry Hind, Lidoderm's inventor, and attested to the efficacy of Lidoderm for both on- and off-label applications. Two studies were not funded by Lidoderm-related entities, and were, at best, non-conclusive. The remaining favorable off-label study was submitted by Dr. Bradley Galer, and was allegedly prepared with no Endo-associated direction or funding, in spite of Dr. Galer's well-documented association with Endo. Interestingly, on September 27, 2000, almost one year to the day after Dr. Galer submitted his first off-label Lidoderm study, Endo hired him as Vice President for Scientific Affairs. Dr. Galer thereafter authored numerous additional, Endo-funded off-label Lidoderm studies, the release of which directly correlates to increased off-label sales.

30) The June 2002 edition of *The Journal of Family Practice* contained a study of PHN treatment options authored by doctors B.S. Alper and P.R. Lewis which was not funded by Endo. The study concluded PHN was best treated with antidepressants and not the lidocane patch, which was listed under the rubric "Therapies Not Proved Effective." The study found fault with the methodology of trials submitted to the FDA in support of Lidoderm's application for orphan drug status. When Drs. Alper and Lewis reviewed the results of those trials, they concluded there was no significant difference in pain reduction when the patch was compared with a placebo.

31) In the October 2002 issue of the same journal, Dr. Galer, who was Endo's Vice President of Scientific Affairs during that period in time, vigorously criticized the Alper-Lewis

study by citing two other studies which concluded otherwise. However, the two studies cited by Dr. Galer, conducted by C. Argoff and N. Katz, et al., were both financed by Endo. Dr. Galer also cited an article in the *New England Journal of Medicine* authored by Dr. Peter Watson which states, "the results of randomized, controlled trials have supported the use of the . . . lidocaine skin patch." Dr. Galer failed to mention that those trials were administered under his direction and funded with a grant from Dr. Hind, Lidoderm's inventor. Responding to Dr. Galer's comments in the same journal issue, Drs. Alper and Lewis took issue with the methodology and validity of the studies cited by Dr. Galer and concluded, ". . . we do not find convincing evidence that the lidocaine patch is more effective than placebos for unselected patients with PHN . . ."

32) Another non-Endo-financed study conducted by doctors W. Khaliq, S. Alam, and N. Puri and published by *The Cochrane Library* 2008, Issue 4, involved randomized trials of 182 PHN patients, and concluded, "there is insufficient evidence to recommend topical lidocaine as a first-line agent in the treatment of PHN. . ." The authors went on to cite a 1996 Rowbotham-Galer study that concluded Lidoderm was effective for the treatment of PHN, and stated the study was missing data. When the authors located and analyzed that missing data, they concluded "the missing data . . . indicated no statistical differences between participants receiving topical lidocaine or placebo in relieving pain, except in participants who were treated three to four weeks. Even in [that] group of participants, there was only a slight improvement in pain relief. . ." Although the duration of PHN pain is variable, this statement is significant, as the diminution of pain three to four weeks after an initial attack may be attributable to normal physiological resolution as opposed to any form of treatment.

33) A common thread in the Endo-financed off-label studies was their authorship by one or more of the following: Dr. Bradley Galer, Dr. Michael Rowbotham, and Dr. Robert H. Dworkin. A 2006 class action filing at the U.S. District Court of Massachusetts against the manufacturers of Neurontin, Pfizer, Inc./Warner-Lambert alleged that *the very same doctors*, Galer, Rowbotham, and Dworkin, as well as Dr. Peter Watson, mentioned above, were paid by Pfizer to present false and misleading information about Neurontin's efficacy for off-label applications.

34) On October 28, 2008, Dr. Adriane Fugh-Berman of Georgetown University Medical Center authored a document entitled, "Off-Label Promotion, On-Target Sales," which described a deceptive scheme wherein pharmaceutical companies seek a "decoy" orphan drug status to expedite FDA reviews and to conceal an intended off-label campaign. Dr. Fugh-Berman has provided expert testimony against pharmaceutical companies that have engaged in this practice. In implementing this scheme, once a drug is approved for the decoy indication, nationally known, influential academic physicians are hired to create a marketing "buzz," which is immediately followed by direct mailings, press releases and journal advertising. The end result is often the creation of a new market for an unapproved drug of dubious value. If Endo's marketing of Lidoderm did not serve as the very prototype for Dr. Fugh-Berman's article, it most assuredly could have. Dr. Fugh-Berman concluded her document with the following poignant admonition:

> "States and other jurisdictions have a duty to protect the health of the public. Allowing off-label promotion of drugs for untested, unproven benefits maximizes industry profits at the expense of public health. A risk-benefit ratio cannot be

assessed without knowing whether benefits exist. Where no benefits exist, no risk is acceptable."

35) Endo also devised a marketing strategy whereby its sales force would promote the off-label use of Lidoderm to physicians. At a sales conference attended by Endo's sales representatives, the representatives were informed that only 2% of Lidoderm prescriptions are for PHN. Endo instructed its sales representatives to inform physicians that Lidoderm is effective in treating carpal tunnel syndrome, osteoarthritis, low back pain, and several other conditions. Endo further provided its representatives with literature and publications touting Lidoderm's off-label usage to treat conditions other than PHN. Endo's management actively promoted Lidoderm for off-label purposes by training its sales representatives to push the use of Lidoderm from its only FDA-approved indication to any type of neuropathic pain.

36) Endo intended for the materials provided to its sales representatives to be used to encourage sales representatives to market Lidoderm to physicians for off-label usage and for the materials to be provided to physicians in order to encourage physicians to prescribe Lidoderm for the treatment of conditions other than PHN. For example, in spite of the requirement imposed upon sales representatives to treat Dr. Galer's 1999 off-label study as restricted material, during the second quarter of 2002 it was mailed, unsolicited, to 40,000 physicians. The restricted material was mailed, not by rogue sale representatives, but by Endo's marketing department. Subsequent to the mailing, Lidoderm sales skyrocketed. Between the second quarter of 2002 and the second quarter of 2003, sales nearly doubled, going from $25,834,000 to $50,617,000. The vast majority of these sales were for off-label uses.

37) In addition, Endo paid kickbacks to physicians in order to encourage them to prescribe Lidoderm for off-label purposes. For example, physicians who were "high prescribers"

of Lidoderm for off-label purposes were given honorariums to present at medical conferences and round table dinners. The doctors were chosen by the local sales representative once they were identified as high prescribers. The round table included informal discussions which concerned the off-label use of Lidoderm.

38) Although the number of patients suffering from PHN has remained relatively constant, net sales of Lidoderm were $309.2 million in 2004, a 73% increase from 2003. Since 2004, Lidoderm's net sales have more than doubled. In 2007, Lidoderm accounted for $705.6 million, or 65% of Endo's total net sales for the year. This dramatic growth in sales is directly attributable to Endo's aggressive, illegal marketing practices.

False Claims

39) Endo knows that a substantial amount of the prescriptions for Lidoderm were and continue to be paid for by Medicaid programs throughout the United States. Endo also has knowledge that a significant number of Lidoderm prescriptions have been paid for by the Medicare Part D prescription drug program which went into effect on January 1, 2006.

40) According to the Drug Utilization Reports available through the Florida Agency for Health Care Administration, Medicaid Pharmacy Services website, the total payments made by the Florida Medicaid program for Lidoderm prescriptions from 2003 until 2008 amount to more than $40 million. In the state of New York, Lidoderm prescriptions amounting to more than $20 million were paid for by Medicaid in the calendar year 2003.

41) Physicians and pharmacists participating in the Medicaid program are required to sign a provider agreement with their resident state. These agreements require providers to comply with all Medicaid requirements. In the state of Florida, for example, Fla. Stat. § 409.907 governs Medicaid provider agreements and states that each "provider agreement shall require the

provider to comply fully with all state and federal laws pertaining to the Medicaid program." Most states also require providers to certify that the provider is in compliance with all Medicaid requirements. Even in states without a certification requirement, all providers' participation in the Medicaid program is conditioned on compliance with all state and federal statutes and regulations.

42) Medicaid claims for the payment of off-label Lidoderm prescriptions are filed with the states by the pharmacists who fill the Medicaid patients' prescriptions. Typically the pharmacist filling the prescription does not have knowledge whether the prescription is on-label or off-label. As a result, a pharmacist generally would not have knowledge as to whether the prescription is for a medically acceptable use and, accordingly, whether the prescription is under the circumstances a covered outpatient drug.

43) Even so, because off-label prescriptions are not eligible for Medicaid or Medicare reimbursement, submission of a Medicaid or Medicare claim for an off-label prescription is a false claim under the False Claims Act, 31 U.S.C. § 3729. The submission of Medicaid claims for off-label Lidoderm prescriptions also violates the State False Claims Acts referenced in this complaint. Endo has knowingly caused false claims to be submitted, and therefore, is liable for the false claims submitted by unwitting pharmacists. As a result of Endo's fraudulent conduct, the Medicare program, as well as the Medicaid programs in the states of Florida, New York, Massachusetts, California, Virginia, Delaware, Illinois, Nevada, Georgia, Hawaii, Indiana, Montana, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, Tennessee, and Texas, have suffered monetary damages.

44) Endo knows that off-label prescriptions for Lidoderm are not eligible for Medicaid and/or Medicare reimbursement. Nevertheless, Endo knowingly and intentionally

sought to increase the number of off-label prescriptions for Lidoderm. Without Endo's efforts to encourage and solicit providers to prescribe Lidoderm for off-label uses, most of the ineligible claims for payment of off-label Lidoderm prescriptions would not have been filed. Since it was first introduced to the marketplace in September 1999, Endo has derived more than $4 billion in income from the sale of Lidoderm. Conservative estimates indicate at least 15% of Lidoderm sales have been reimbursed by government-funded healthcare plans. Endo's own calculations confirm more than 90% of all Lidoderm prescriptions are written off-label. Consequently, the amount of reimbursement expended by government healthcare plans for off-label Lidoderm prescriptions is conservatively estimated at more than $540 million.

COUNT I
Violation of False Claims Act, 31 U.S.C. § 3729(a)

45) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

46) This count sets forth claims for treble damages and forfeitures under the federal False Claims Act, 31 U.S.C. §§ 3729-3732, as amended.

47) Through the acts described above, including Defendant's violations of federal anti-kickback laws, Defendant and its agents and employees knowingly caused to be presented to the United States Government fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid and Medicare programs.

48) Defendant has knowingly violated:

(a) 31 U.S.C. § 3729(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) 31 U.S.C. § 3729(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; and/or

(c) 31 U.S.C. § 3729(a)(3) by conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid.

49) The United States, unaware of the falsity of the claims, approved, paid, and participated in payments made by the United States for claims that otherwise would not have been allowed.

50) By reason of Defendant's false claims, the United States has been damaged and possibly continues to be damaged.

COUNT II
Violation of Florida False Claims Act, Fla. Stat. §68.082(2)

51) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

52) This count sets forth claims for treble damages and forfeitures under the Florida False Claims Act.

53) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Florida Medicaid program fraudulent claims, records,

and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

54) Defendant has knowingly violated:

(a) Fla. Stat. §68.082(2)(a) by knowingly presenting, or causing to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) Fla. Stat. §68.082(2)(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; and/or

(c) Fla. Stat. §68.082(2)(c) by conspiring to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

55) The State of Florida unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Florida for claims that otherwise would not have been allowed.

56) By reason of Defendant's fraudulent activities, the State of Florida has been damaged, and possibly continues to be damaged.

COUNT III
Violation of New York False Claims Act, N.Y. State Fin. Law § 189.1

57) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

58) This count sets forth claims for treble damages and forfeitures under the New York False Claims Act.

59) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the New York Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

60) Defendant has knowingly violated:

(a) N.Y. State Fin. Law § 189.1(a) by knowingly presenting, or causing to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) N.Y. State Fin. Law § 189.1(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government; and/or

(c) N.Y. State Fin. Law § 189.1(c) by conspiring to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

61) The State of New York unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of New York for claims that otherwise would not have been allowed.

62) By reason of Defendant's fraudulent activities, the State of New York has been damaged, and possibly continues to be damaged.

COUNT IV
Violation of the Massachusetts False Claims Act, M. G. L. A. ch. 12 § 5B

63) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

64) This count sets forth claims for treble damages and forfeitures under the

Massachusetts False Claims Act.

65) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Massachusetts Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

66) Defendant knowingly violated:

(a) M. G. L. A. ch. 12 § 5B(1) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;

(b) M. G. L. A. ch. 12 § 5B(2) by knowingly making, using, or causing to be used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof; and/or

(c) M. G. L. A. ch. 12 § 5B(3) by conspiring to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim.

67) The State of Massachusetts, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Massachusetts for claims that otherwise would not have been allowed.

68) By reason of Defendant's fraudulent activities, the State of Massachusetts has been damaged, and possibly continues to be damaged.

COUNT V
Violation of the California False Claims Act, Cal. Govt. Code § 12651(a)

69) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

70) This count sets forth for treble damages and forfeitures under the California False Claims Act.

71) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the California Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

72) Defendant knowingly violated:

(a) Cal. Govt. Code § 12561(a)(1) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;

(b) Cal. Govt. Code § 12561(a)(2) by knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; and/or

(c) Cal. Govt. Code § 12561(a)(3) by conspiring to commit a violation of Cal. Govt. Code § 12561(a).

73) The State of California, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of California for claims that otherwise would not have been allowed.

74) By reason of Defendant's fraudulent activities, the State of California has been damaged, and possibly continues to be damaged.

COUNT VI
Violation of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)

75) Relator realleges and incorporates by reference the allegations of paragraphs 1-44

of this complaint.

76) This count sets forth claims for treble damages and forfeitures under the Virginia Fraud Against Taxpayers Act.

77) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Virginia Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

78) Defendant knowingly violated:

(a) Va. Code Ann. § 8.01-216.3(A)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;

(b) Va. Code Ann. § 8.01-216.3(A)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim pair or approved by the Commonwealth; and/or

(c) Va. Code Ann. § 8.01-216.3(A)(3) by conspiring to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid.

79) The State of Virginia, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Virginia for claims that otherwise would not have been allowed.

80) By reason of Defendant's fraudulent activities, the State of Virginia has been damaged, and possibly continues to be damaged.

COUNT VII
Violation of Delaware False Claims and Reporting Act, 6 Del. C § 1201(a)

81) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

82) This count sets forth claims for treble damages and forfeitures under the Delaware False Claims and Reporting Act.

83) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Delaware Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

84) Defendant has knowingly violated:

(a) 6 Del. C § 1201(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

(b) 6 Del. C § 1201(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; and/or

(c) 6 Del. C § 1201(a)(3) by conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid.

85) The State of Delaware, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Delaware for claims that otherwise would not have been allowed.

86) By reason of Defendant's fraudulent activities, the State of Delaware has been

damaged, and possibly continues to be damaged.

COUNT VIII
Violation of Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)

87) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

88) This count sets forth claims for treble damages and forfeitures under the Illinois Whistleblower Reward and Protection Act.

89) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Illinois Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

90) Defendant has knowingly violated:

(a) 740 Ill. Comp. Stat. § 175/3(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;

(b) 740 Ill. Comp. Stat. § 175/3(a)(2) by knowingly making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or

(c) 740 Ill. Comp. Stat. § 175/3(a)(3) by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid.

91) The State of Illinois, unaware of the falsity of the claims, approved, paid, and

participated in payments made by the State of Illinois for claims that otherwisw would not have been allowed.

92) By reason of Defendant's fraudulent activities, the State of Illinois has been damaged, and possibly continues to be damaged.

COUNT IX
Violation of Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040(1)

93) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

94) This count sets forth claims for treble damages and forfeitures under the Nevada False Claims Act.

95) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Nevada Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

96) Defendant has knowingly violated:

(a) Nev. Rev. Stat. Ann. § 357.040(1)(a) by knowingly presenting or causing to be presented a false claim for payment or approval;

(b) Nev. Rev. Stat. Ann. § 357.040(1)(b) by knowingly making or using, or causing to be made or used, a false record or statement to obtain payment or approval of a false claim; and/or

(c) Nev. Rev. Stat. Ann. § 357.040(1)(c) by conspiring to defraud by obtaining allowance or payment of a false claim.

97) The State of Nevada, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Nevada for claims that otherwise would not have been allowed.

98) By reason of Defendant's fraudulent activities, the State of Nevada has been damaged, and possibly continues to be damaged.

COUNT X
Violation of Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a)

99) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

100) This count sets forth claims for treble damages and forfeitures under the Georgia False Medicaid Claims Act.

101) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Georgia Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

102) Defendant has knowingly violated:

(a) O.C.G.A. § 49-4-168.1(a)(1) by knowingly presenting or causing to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(b) O.C.G.A. § 49-4-168.1(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program; and/or

(c) O.C.G.A. § 49-4-168.1(a)(3) by conspiring to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

103) The State of Georgia, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Georgia for claims that otherwise would not have been allowed.

104) By reason of Defendant's fraudulent activities, the State of Georgia has been damaged, and possibly continues to be damaged.

COUNT XI
Violation of Hawaii False Claims Act, Haw. Rev. Stat. §661-21(a)

105) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

106) This count sets forth claims for treble damages and forfeitures under the Hawaii False Claims Act.

107) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Hawaii Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

108) Defendant has knowingly violated:

(a) Haw. Rev. Stat. §661-21(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(b) Haw. Rev. Stat. §661-21(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or

(c) Haw. Rev. Stat. §661-21(a)(3) by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid.

109) The State of Hawaii, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Hawaii for claims that otherwise would not have been allowed.

110) By reason of Defendant's fraudulent activities, the State of Hawaii has been damaged, and possibly continues to be damaged.

COUNT XII
Violation of Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-2(b)

111) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

112) This count sets forth claims for treble damages and forfeitures under the Indiana False Claims and Whistleblower Protection Act.

113) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Indiana Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

114) Defendant knowingly violated:

(a) Ind. Code Ann. §5-11-5.5-2(b)(1) by knowingly or intentionally presenting a false claim to the State for payment or approval;

(b) Ind. Code. Ann. §5-11-5.5-2(b)(2) by knowingly or intentionally making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim approved by the State;

(c) Ind. Code Ann. §5-11-5.5-2(b)(7) by conspiring with another person to perform an act described in §5-11-5.5-2(b)(1)-(6); and/or

(d) Ind. Code Ann. §5-11-5.5-2(b)(8) by causing or inducing another person to perform an act described in §5-11-5.5-2(b)(1)-(6).

115) The State of Indiana, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Indiana for claims that otherwise would not have been allowed.

116) By reason of Defendant's fraudulent activities, the State of Indiana has been damaged, and possibly continues to be damaged.

COUNT XIII
Violation of Montana False Claims Act, Mont. Code Ann. §17-8-403(1)

117) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

118) This count sets forth claims for treble damages and forfeitures under the Montana False Claims Act.

119) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Montana Medicaid program fraudulent claims, records,

and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

120) Defendant knowingly violated:

(a) Mont. Code Ann. §17-8-403(1)(a) by knowingly presenting, or causing to be presented, to an officer or employee of the government entity a false claim for payment or approval;

(b) Mont. Code Ann. §17-8-403(1)(b) by knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the government entity; and/or

(c) Mont. Code Ann. §17-8-403(1)(c) by conspiring to defraud the government entity by getting a false claim allowed or paid by the government entity.

121) The State of Montana, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Montana for claims that otherwise would not have been allowed.

122) By reason of Defendant's fraudulent activities, the State of Montana has been damaged, and possibly continues to be damaged.

COUNT XIV
Violation of New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61-b(1)

123) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

124) This count sets forth claims for treble damages and forfeitures under the New

Hampshire False Claims Act.

125) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the New Hampshire Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

126) Defendant knowingly violated:

(a) N.H. Rev. Stat. Ann. §167:61-b(1)(a) by knowingly presenting, or causing to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval;

(b) N.H. Rev. Stat. Ann. §167:61-b(1)(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department; and/or

(c) N.H. Rev. Stat. Ann. §167:61-b(1)(c) by conspiring to defraud the department by getting a false or fraudulent claim allowed or paid.

127) The State of New Hampshire, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of New Hampshire for claims that otherwise would not have been allowed.

128) By reason of Defendant's fraudulent activities, the State of New Hampshire has been damaged, and possibly continues to be damaged.

COUNT XV
Violation of the New Jersey False Claims Act, N.J.S.A. §2A:32C-3

129) Relator reallages and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

130) This count sets forth claims for treble damages and forfeitures under the New Jersey False Claims Act.

131) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the New Jersey Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

132) Defendant has knowingly violated:

(a) N.J.S.A. §2A:32C-3(a) by knowingly presenting, or causing to be presented, to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) N.J.S.A. §2A:32C-3(b) by knowingly making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or

(c) N.J.S.A. §2A:32C-3(c) by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

133) The State of New Jersey, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of New Jersey for claims that otherwise would not have been allowed.

134) By reason of Defendant's fraudulent activities, the State of New Jersey has been damaged, and possibly continues to be damaged.

COUNT XVI

Violation of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-4

135) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

136) This count sets forth claims for treble damages and forfeitures under the New Mexico Medicaid False Claims Act.

137) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the New Mexico Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

138) Defendant has knowingly violated:

(a) N.M. Stat. Ann. §27-14-4(A) by presenting, or causing to be presented, to the State a claim for payment under the Medicaid program knowing that such a claim is false or fraudulent;

(b) N.M. Stat. Ann. §27-14-4(C) by making, using, or causing to be made or used, a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the State knowing such record or statement is false; and/or

(c) N.M. Stat. Ann. §27-14-4(D) by conspiring to defraud the State by getting a claim allowed or paid under the Medicaid program knowing that such a claim is false or fraudulent.

139) The State of New Mexico, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of New Mexico for claims that otherwise would not have been allowed.

140) By reason of Defendant's fraudulent activities, the State of New Mexico has been damaged, and possibly continues to be damaged.

COUNT XVII
Violation of Oklahoma Medicaid False Claims Act, §63-5053.1(B)

141) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

142) This count sets forth claims for treble damages and forfeitures under the Oklahoma Medicaid False Claims Act.

143) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Oklahoma Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

144) Defendant has knowingly violated:

(a) §63-5053.1(B)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State of Oklahoma a false or fraudulent claim for payment or approval;

(b) §63-5053.1(B)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or

(c) §63-5053.1(B)(3) by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid.

145) The State of Oklahoma, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Oklahoma for claims that otherwise would not have been allowed.

146) By reason of Defendant's fraudulent activities, the State of Oklahoma has been damaged, and possibly continues to be damaged.

COUNT XVIII
Violation of Rhode Island State False Claims Act, 9-1.1-3

147) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

148) This count sets forth claims for treble damages and forfeitures under the Rhode Island False Claims Act.

149) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Rhode Island Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

150) Defendant has knowingly violated:

(a) 9-1.1-3(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State or a member of the guard a false or fraudulent claim for payment or approval;

(b) 9-1.1-3(2) by knowingly making, using, or causing to be made or used a false

record or statement to get a false or fraudulent claim paid or approved by the State; and/or

(c) 9-1.1-3(3) by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid.

151) The State of Rhode Island, unaware of the falsity of the claims, approved, paid and participated in payments made by the State of Rhode Island for claims that otherwise would not have been allowed.

152) By reason of Defendant's fraudulent activities, the State of Rhode Island has been damaged, and possibly continues to be damaged.

COUNT XIX
Violation of Tennessee Medicaid False Claims Act, Tenn. Code Ann. §71-5-182(a)

153) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

154) This count sets forth claims for treble damages and forfeitures under the Tennessee Medicaid False Claims Act.

155) Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Tennessee Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

156) Defendant knowingly violated:

(a) Tenn. Code Ann. §71-5-182(a)(1)(A) by presenting, or causing to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

(b) Tenn. Code Ann. §71-5-182(a)(1)(B) by making, using, or causing to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid or approved by the State knowing such record or statement is false; and/or

(c) Tenn. Code Ann. §71-5-182(a)(1)(C) by conspiring to defraud the State by getting a claim allowed or paid under the Medicaid program, knowing such claim is false or fraudulent.

157) The State of Tennessee, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Tennessee for claims that otherwise would not have been allowed.

158) By reason of Defendant's fraudulent activities, the State of Tennessee has been damaged, and possibly continues to be damaged.

COUNT XX
Violation of Texas False Claims Act, Tex. Hum. Res. Code §36.002

159) Relator realleges and incorporates by reference the allegations of paragraphs 1-44 of this complaint.

160) This count sets forth claims for treble damages and forfeitures under the Texas False Claims Act.

161) Through the acts described above, Defendant and its agents and employees

knowingly caused to be presented to the Texas Medicaid program fraudulent claims, records, and statements in order to obtain reimbursement for off-label prescriptions paid for by the Medicaid program.

162) Defendant has knowingly violated:

(a) Tex. Hum. Res. Code §36.002(1) by knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

163) The State of Texas, unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Texas for claims that otherwise would not have been allowed.

164) By reason of Defendant's fraudulent activities, the State of Texas has been damaged, and possibly continues to be damaged.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Relator requests that judgment be entered against Defendant, ordering that:

a. Defendant cease and desist from violating the Federal False Claims Act and the above referenced State False Claims Acts;

b. Defendant pay an amount equal to three times the amount of damages the United States and the States have sustained because of Defendant's actions;

c. Defendant pay the maximum civil penalties allowable to be imposed for each false or fraudulent claim presented to the United States and each false or fraudulent claim

presented to the States;

d. Plaintiff/Relator be awarded the maximum amount allowed pursuant the Federal False Claims Act and the State False Claims Acts;

e. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs; and

f. United States and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Relator hereby demands a trial by jury.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been furnished by Certified Mail, Return Receipt Requested, this 6TH day of January, 2011 to the following:

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